(19)	Europäisches Patentamt European Patent Office Office européen des brevets	(11) EP 1 736 125 A1					
(12)	EUROPEAN PATE	INT APPLICATION					
(43)	Date of publication: 27.12.2006 Bulletin 2006/52	(51) Int Cl.: A61F 5/443 <sup>(2006.01)</sup> A61F 5/448 <sup>(2006.01)</sup>					
(21)	Application number: 06120792.4						
(22)	22) Date of filing: 16.01.2004						
(84)	Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR	<ul> <li>Smith, Rory c/o Clinimed (Holdings) Limited High Wycombe Buckinghamshire HP10 9QY (GB)</li> </ul>					
(30)	Priority: 16.01.2003 GB 0300992	(74) Representative: Fitchett, Stuart Paul Saunders & Dolleymore					
(62)	Document number(s) of the earlier application(s) in accordance with Art. 76 EPC: 04702742.0 / 1 587 467	European Patent Attorneys 9 Rickmansworth Road Watford WD18 0JU (GB)					
(71)	Applicant: CLINIMED (Holdings) LIMITED High Wycombe, Bucks HP10 9QY (GB)	Remarks: This application was filed on 15 - 09 - 2006 as a divisional application to the application mentioned under INID code 62.					
(72)	Inventors: May, Owen c/o Clinimed (Holdings) Limited High Wycombe Buckinghamshire HP10 9QY (GB)						

# (54) A support for an ostomy bag

(57) The present invention provides a support (1) for an ostomy bag (7), the support extending the flange of the ostomy bag to reduce the risk of leakage. The support (1) is formed of a hydrocolloid layer (2) shaped to fit around a flange (9) of the ostomy bag. The support can be fitted to the flange at any appropriate location enabling the flange to be supported at the point at which it is prone to failing on a particular wearer.



EP 1 736 125 A1

Printed by Jouve, 75001 PARIS (FR)

15

### Description

**[0001]** The present invention relates to a support for an ostomy bag, but is also applicable to wound drainage bags. For the purposes of the present specification, including the claims, all references to ostomy bags are to be interpreted to include wound-drainage bags and wound managers.

**[0002]** The main types of ostomy bags are colostomy bags, ileostomy bags and urostomy bags. These together with wound drainage or wound manager bags have in common that they form a seal around the stoma, or wound, through which waste material is drained from the body.

**[0003]** Ostomy bags comprise a receptacle for the waste having an aperture for receiving the waste. This aperture is normally surrounded by a flange of hydrocolloid adhesive. Hydrocolloid adhesive is particularly "skin friendly" comprising approximately 20% gelatine, 20% pectin and 20% carboxymethyl cellulose in an organic matrix of polyisobutylene, which comprises the remaining 40% of the hydrocolloid adhesive.

**[0004]** The proportions of the components of the hydrocolloid adhesive may vary, but an important property of the material is that it is breathable. This is important because a particular problem with ostomy bags arises from the extended periods for which they have to be worn by a patient, normally 24 hours a day. This commonly results in maceration where the skin cannot breath and becomes saturated.

**[0005]** The wear time of an ostomy bag is often limited by the seal about the flange failing, whereby waste fluids from the body may leak past the seal, requiring the wearer to replace the ostomy bag, thus replacing the seal formed with the bag. This leakage is not only unpleasant and potentially embarrassing for the wearer, but the waste is also corrosive to the skin when the skin is exposed to the waste for any significant period of time. This together with any maceration that may occur reduces the likelihood of any subsequent ostomy bag correctly sealing.

**[0006]** Increasing the flange size on an ostomy bag might be thought to improve the sealing ability of the flange, however it is not desired to provide an excessively large flange because this in turn will expose a larger area of skin to the possible risk of maceration and also cause problems due to the flexing of the body under the area of the flange.

**[0007]** Ostomy bags thus normally have a standard size of flange that is considered appropriate for the "average" wearer. However, all wearers are different and some find that the standard flange of an ostomy bag does not seal, or fails before the ostomy bag is full. This often arises where there are bony protuberances close to the stoma or where stomal hernias arise, often as a side effect of the skin being cut to form the stoma.

**[0008]** There are currently two products available to a wearer who suffers problems with leaking ostomy bags. The first is hydrocolloid strip, formed by extruding and

rolling hydrocolloid material. The strip is cut to length by a wearer and applied in the area where the flange seal normally fails. An alternative product used by some ostomy bag wearers is sold under the trade mark "SECU-

<sup>5</sup> PLAST". This comprises an annular disk of tape covered with an acrylic adhesive. This is placed behind and around the flange of an ostomy bag thereby extending the flange. However, a problem with this material is the acrylic adhesive is not as "skin friendly" as the hydrocol-

<sup>10</sup> loid material and tends to increase skin trauma, which in turn causes problems with the subsequent fitting of further ostomy bags.

**[0009]** According to the present invention there is provided a support for an ostomy bag comprising a layer of hydrocolloid shaped to fit around and extend a portion of

a flange of an ostomy bag.

**[0010]** Employing the present invention enables a wearer to fit a support in accordance with the present invention to that portion of the flange of an ostomy bag

20 that is most prone to fail, when fitted to that particular wearer. The shaping of the layer of hydrocolloid, to fit around and extend the flange, ensures a large section of the circumference of the flange is extended whilst minimising the additional area of skin covered.

<sup>25</sup> **[0011]** The invention is particularly advantageous in that it permits a standard support or range of supports to be used with one or more standard ostomy bags.

**[0012]** The hydrocolloid is self-adhesive on one side and covered by release paper arranged to be removed <sup>30</sup> prior to use. This permits the hydrocolloid to be correctly positioned partially behind the flange and the release paper removed, such that the hydrocolloid support can be adhered to the flange in the correct position and, where the flange is provided with a similar release paper, the

<sup>35</sup> release paper of the flange then removed prior to mounting the ostomy bag upon the wearer.

**[0013]** Preferably, the hydrocolloid is semi-circular in shape, thus corresponding closely to the shape of the flange of the ostomy bag. Two hydrocolloid supports may

40 be arranged in an opposed position about the flange, so that they extend around the complete circumference of the flange, thereby enabling the whole flange to be extended, where this is desired by a particular wearer.

[0014] The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which like numerals are used throughout to indicate like parts, and of which:

Figure 1A is a plan view of a support in accordance with the present invention;

Figure 1B is a side elevation of the support of Figure 1A;

Figure 2 is a perspective view of the support of Figures 1A and 1B;

Figure 3 is a perspective view of the support of Figure 2, showing the release paper partially peeled back; Figure 4 illustrates an ostomy bag fitted with a support in accordance with present invention; and

50

55

5

15

30

35

40

45

Figure 5 illustrates an ostomy bag fitted with two supports in accordance with present invention.

**[0015]** Referring to Figures 1A, 1B and 2, a support for an ostomy bag in accordance with the present invention, indicated generally as 1, comprises a layer of 0.6 mm thick Hyperflex<sup>TM</sup> hydrocolloid, an EU40 25 $\mu$ m thick polyurethane film backing 3 and a release paper divided by two cuts 4 and 5 into three sections 6a, 6b and 6c, the release paper being standard sterling coated paper. The properties of the hydrocolloid material 2 and polyurethane film 3 are such that the support 1 is breathable when the release paper 6a, 6b, 6c is removed.

**[0016]** Figure 3 illustrates how the support 1 can be slightly flexed in the region of the slit 4 permitting the release paper to be held and peeled back. The release paper can similarly be removed starting at the slit 5.

**[0017]** Referring to Figure 4, there is illustrated a standard ostomy bag, illustrated generally as 7, comprising a receptacle portion 8, for receiving waste, and a flange 9. 20 The flange 9 is formed of hydrocolloid material and has a release paper on its upper surface 10. In use the release paper is removed and the flange 9 centred on a stoma or wound of the wearer, such that fluid drains from the stoma or wound into the receptacle 8, via aperture 11 in 25 the flange 9.

**[0018]** The support 1 of the present invention is placed in any desired position about the flange 9, and then slid partly behind the flange with the release paper 6a, 6b, 6c uppermost, as shown. In this position, starting at one of the slits 4 or 5, the release papers are peeled from the support 1 and the support adhered to the flange 9. Then the release paper (not shown) of the flange 9 is removed from the uppermost surface 10 and the flange 9 and support 1 simultaneously adhered to the wearer.

**[0019]** As shown in Figure 5, a number of supports in accordance with the invention may be used on an ostomy bag, either to completely surround the flange as shown in Figure 5, to further extend the flange in a particular direction, that is to say further than it could be extended by use of a single support, or a number of supports may be built up in depth so as to account for any depression in the surface of the wearer adjacent a stoma. Although not illustrated, it is possible that supports of different sizes may also be provided.

**[0020]** The present invention has been illustrated by way of example only and further embodiments may be apparent within the scope of the appended claims.

#### Claims

 A support (1) for an ostomy bag (7) comprising a layer of hydrocolloid (2) shaped to fit around and extend a portion of a flange (9) of an ostomy bag, wherein the layer of hydrocolloid (2) is self-adhesive on one side, the said self-adhesive side of the hydrocolloid layer is covered by a release paper (6) arranged to be removed prior to use, **characterised in that** the release paper (6) is divided by two cuts (4, 5) into three so that it has two end sections (6a, 6c) and a middle section (6b).

- **2.** A support (1) as claimed in claim 1 wherein the hydrocolloid layer (2) is semicircular.
- A support (1) as claimed in any preceding claim, arranged to cooperate with a similar support (1) to form a collar extending around the complete circumference of the flange (9).

50

55















European Patent

Office

### PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 06 12 0792 shall be considered, for the purposes of subsequent proceedings, as the European search report

	DOCUMENTS CONSID	ERED TO BE RELEVANT		
Category	Citation of document with ir of relevant pass	ndication, where appropriate, ages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
х	US 3 039 464 A (ESP 19 June 1962 (1962- * the whole documen	PERANZA GALINDO) 06-19) 1t *	1-3	INV. A61F5/443 A61F5/448
х	US 2003/004477 A1 ( ET AL) 2 January 20 * paragraphs [0077]	GOTHJAELPSEN LAILA BUSK 03 (2003-01-02) - [0081]; figure 9 *	1-3	
Х	WO 02/05735 A (HOOD 24 January 2002 (20 * page 12, line 4 -	1-3		
A	US 5 384 174 A (WAR 24 January 1995 (19 * column 5, line 67 figure 2 *	D WILLIAM J [GB] ET AL) 95-01-24) - column 6, line 10;	1-3	
A	EP 0 793 951 A1 (SQ [US]) 10 September * column 6, lines 4 * column 7, lines 2	UIBB BRISTOL MYERS CO 1997 (1997-09-10) 7-56 * 2-48; figure 4 *	1-3	TECHNICAL FIELDS SEARCHED (IPC)
A	GB 2 152 387 A (HOL 7 August 1985 (1985 * page 2, lines 88-	LISTER INC) -08-07) 117; figures 1,9 *	1-3	A61F
The Searc not compl be carried Claims se Claims no Reason fo	b) Division considers that the present y with the EPC to such an extent that out, or can only be carried out partial arched completely : arched incompletely : it searched : or the limitation of the search:			
see	sheet C			
	Place of search	Date of completion of the search		Examiner
	Munich	20 November 2006	Kra	ssow, Heiko
C/ X : parti Y : parti docu A : tech	ATEGORY OF CITED DOCUMENTS icularly relevant if taken alone icularly relevant if combined with anot ment of the same category nological background	าvention shed on, or		



European Patent Office

# INCOMPLETE SEARCH SHEET C

Application Number EP 06 12 0792

Claim(s) not searched: 6

Reason for the limitation of the search:

Claim 6 seeks to define the invention by reference to the figures, and without defining any technical features (Article 6.2 PCT). The resulting lack of clarity is such that it is impossible to exactly determine the scope for which protection is sought rendering a meaningful search impossible.

### EP 1 736 125 A1

#### ANNEX TO THE EUROPEAN SEARCH REPORT **ON EUROPEAN PATENT APPLICATION NO.**

EP 06 12 0792

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-11-2006

	Patent document cited in search report		Publication date		Patent family member(s)		Publication date
	US 3039464	Α	19-06-1962	NONE			
	US 2003004477	A1	02-01-2003	AT AU CA CN WO EP ES JP NO	320779 721675 4616397 2269575 1233945 9817212 0998247 2260801 2001502570 991905	T B2 A A1 A1 A1 T3 T A	$15-04-2006 \\ 13-07-2000 \\ 15-05-1998 \\ 30-04-1998 \\ 03-11-1999 \\ 30-04-1998 \\ 10-05-2000 \\ 01-11-2006 \\ 27-02-2001 \\ 22-06-1999 \\ 10-05-2000 \\ 10-$
	WO 0205735	A	24-01-2002	AU GB	7638101 2381200	A A	30-01-2002 30-04-2003
	US 5384174	A	24-01-1995	NONE			
	EP 0793951	A1	10-09-1997	AT AU AU CA DE DE DE DE S JP NZ US ZA	264090 218312 705091 1494497 2198515 69712946 69728699 69728699 69728699 793951 2215837 2176606 9313517 314147 5722965 9701614	T T B2 A A1 D1 T2 D1 T2 T3 T3 T3 A A A A A	15-04-2004 15-06-2002 13-05-1999 04-09-1997 29-08-1997 11-07-2002 23-01-2003 19-05-2004 23-09-2004 09-09-2002 16-10-2004 01-12-2002 09-12-1997 26-08-1998 03-03-1998 25-08-1998
FORM P0459	GB 2152387	A	07-08-1985	AU AU CA DE DK ES FR GB HK HK IE	559535 1199883 1190823 3309083 102883 279833 2523435 2116849 52087 83087 53994	B2 A A1 A1 A U A1 A A A B1	$\begin{array}{c} 12 - 03 - 1987 \\ 22 - 09 - 1983 \\ 23 - 07 - 1985 \\ 22 - 09 - 1983 \\ 17 - 09 - 1983 \\ 16 - 11 - 1984 \\ 23 - 09 - 1983 \\ 05 - 10 - 1983 \\ 10 - 07 - 1987 \\ 13 - 11 - 1987 \\ 10 - 05 - 1989 \end{array}$

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

## EP 1 736 125 A1

#### **ANNEX TO THE EUROPEAN SEARCH REPORT** ON EUROPEAN PATENT APPLICATION NO.

EP 06 12 0792

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-11-2006

	Patent document cited in search report		Publication date		Patent family member(s)	Publication date
	GB 2152387	A		JP JP JP SE SE US	1500596 C 58165843 A 63052900 B 454238 B 8301349 A 4445898 A	28-06-1989 30-09-1983 20-10-1988 18-04-1988 17-09-1983 01-05-1984
FORM P0459						

 $\stackrel{\mbox{\tiny V}}{=}$  For more details about this annex : see Official Journal of the European Patent Office, No. 12/82